## EXHIBIT 8

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1
            THE UNITED STATES DISTRICT COURT
            FOR THE EASTERN DISTRICT OF OHIO
2
                    EASTERN DIVISION
3
4
    IN RE: NATIONAL
    PRESCRIPTION OPIATE: MDL NO. 2804
5
    LITIGATION
6
                        : CASE NO.
    THIS DOCUMENT :
                             1:17-MD-2804
    RELATES TO ALL CASES: Hon. Dan A. Polster
8
9
              Wednesday, November 28, 2018
10
11
        HIGHLY CONFIDENTIAL - SUBJECT TO FURTHER
12
                 CONFIDENTIALITY REVIEW
13
14
           Videotaped deposition of JOSEPH
15
    TOMKIEWICZ, taken pursuant to notice, was held
16
    at Golkow Litigation Services, One Liberty
17
    Place, 1650 Market Street, Suite 5150,
18
    Philadelphia, Pennsylvania 19103, beginning at
19
    9:58 a.m., on the above date, before Lisa V.
2.0
    Feissner, RDR, CRR, Notary Public.
2.1
22
23
               GOLKOW LITIGATION SERVICES
           877.370.3377 ph | 917.591.5672 fax
24
                    deps@golkow.com
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- ask you, it's also affected your family; is
- 2 that fair to say?
- A. My family:
- 4 MR. HAMMOUD: Object to the form.
- 5 THE WITNESS: I don't know anyone
- in my family who is a -- has an issue
- 7 with opioids.
- 8 BY MR. CARTMELL:
- 9 Q. But you have good friends?
- 10 A. Oh, yeah, my -- like I said, my
- wife's best friend growing up.
- Q. Okay. Would you agree with me that
- the abuse and addiction of both prescription
- and nonprescription opioids is a serious
- 15 problem?
- A. Well, of course.
- Q. And it affects the health, social,
- and economic welfare of all individuals,
- 19 communities, and companies?
- MR. HAMMOUD: Object to the form.
- THE WITNESS: I would say that's a
- fair assessment.
- BY MR. CARTMELL:
- Q. And you mentioned that opioid

- deaths continue to rise; is that right?
- 2 A. That is correct.
- Q. And in part that's because opioids
- 4 continue to be diverted and abused, correct?
- MR. HAMMOUD: Object to the form.
- THE WITNESS: The rates that I've
- seen involving prescription opioids have
- 8 appeared to be relatively flat over the
- 9 last several years.
- 10 BY MR. CARTMELL:
- Q. Staying at the same level, is that
- what you mean?
- A. Correct, correct.
- Q. In other words, you're not saying
- that it's going down --
- A. Correct.
- Q. -- you're just saying that it's
- 18 been flat?
- A. Correct. And I'm not saying it's
- not an issue either.
- Q. You're saying it's a serious issue,
- 22 aren't you?
- A. Oh, it's a very serious issue, yes.
- Q. Would you agree, and I think you

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said this, that the opioid epidemic is
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- worsening?
- MR. HAMMOUD: Object to the form,
- 4 mischaracterizes prior testimony.
- 5 THE WITNESS: Yeah, it -- in terms
- of what I see with heroin and illicit
- fentanyl -- and that's fentanyl that's
- 8 not produced for medical purposes -- I
- see pretty dramatic increases in those
- products.
- 11 BY MR. CARTMELL:
- Q. And would you agree with me that
- the opioid epidemic must be addressed in part
- 14 through the manufacturers --
- MR. HAMMOUD: Objection.
- 16 BY MR. CARTMELL:
- Q. -- of the opioids?
- A. Well, I think my program has been
- part of helping to solve the problem.
- Q. Right. In other words, you would
- 21 agree with me that in order to solve this
- problem, the manufacturers -- and I'm not
- eliminating any others -- but are a part of
- that solution and have responsibility to do

- their duty to try to limit the amount of
- diverted opioids. Would you agree with that?
- MR. HAMMOUD: Object to the form.
- 4 THE WITNESS: Oh, from -- yeah, we
- 5 have a different responsibility to help
- 6 prevent diversion.
- <sup>7</sup> BY MR. CARTMELL:
- Q. Okay. Let's talk about
- 9 specifically what the law says that duty and
- 10 responsibility is for manufacturers of opioids.
- 11 I talked about this a little bit, but let me
- start from the beginning, if I can, because I
- want to make this very clear to the jurors, and
- <sup>14</sup> understandable.
- 15 Is it true that the sale of opioid
- narcotic drugs is regulated by the law in
- 17 America?
- A. That's fair.
- MR. HAMMOUD: Object to the form.
- 20 BY MR. CARTMELL:
- Q. And for opioid narcotic drugs like
- the ones that Teva sells and distributes, those
- 23 are called controlled substances; is that
- 24 right?

- MR. HAMMOUD: Object to the form.
- THE WITNESS: That is correct.
- 3 BY MR. CARTMELL:
- Q. Okay. And what does it mean for a
- 5 drug or a pharmaceutical like the opioids
- 6 produced by Teva and sold by Teva, what does it
- mean to be a controlled substance?
- A. From my understanding, it is that
- 9 it's a -- that the manufacture, sale,
- distribution of the products are controlled
- 11 federally by the federal government and that --
- and as part of what's called the closed
- distribution system.
- Q. Okay. And I think you mentioned
- this, but Congress actually passed what's
- 16 called the Controlled Substances Act that
- governs and regulates the sale of opioid
- 18 narcotics and controlled substances?
- MR. HAMMOUD: Object to the form.
- THE WITNESS: Correct.
- 21 BY MR. CARTMELL:
- Q. Okay. And I think you mentioned
- this, too, but the Controlled Substances Act
- went into effect in 1970; is that right?

- 1 A. That's correct.
- Q. Okay. I want to actually hand you
- 3 Exhibit 4 in this case and ask you a few
- 4 questions about this document.
- 5 (Exhibit Teva-Tomkiewicz-004 marked
- for identification and attached to the
- 7 transcript.)
- 8 BY MR. CARTMELL:
- 9 Q. This was a document that was
- produced in this litigation by Teva from their
- internal files, and I just have a few questions
- 12 about this letter for you.
- This is a letter dated --
- MR. HAMMOUD: Can you give him a
- second to read the document.
- 16 BY MR. CARTMELL:
- Q. Mr. Tomkiewicz, have you seen this
- 18 letter before?
- 19 A. Yes, I have.
- Q. In other words, you're familiar
- with this letter based on your experience in
- the industry related to diversion control of
- opioid narcotics?
- A. Yes, I've seen it and have a copy

- $^{1}$  of it.
- O. Okay. Now, I think actually we
- found this letter in your file. But as you see
- 4 here, this is from the U.S. Department of
- <sup>5</sup> Justice Drug Enforcement Administration.
- Do you see that?
- 7 A. Yes.
- 8 Q. And we talked -- you kept calling
- 9 it the administration; I kept calling it the
- <sup>10</sup> agency. I apologize.
- A. Administration, yeah.
- Q. But this is the entity that is --
- A. I've been wrong before.
- Q. Don't worry. I am all the time.
- But this is the entity that is charged with the
- duty to enforce the act, the Controlled
- Substances Act, correct?
- A. My understanding, yes.
- Q. Okay. And I want to go through a
- few things here. The date of this is actually
- February 7th of 2007.
- Do you see that?
- A. Yes.
- Q. So that's actually over ten years

- 1 ago, correct?
- 2 A. Correct.
- Q. And this is a letter from, if you
- 4 look at the last page, somebody named Joseph
- 5 Rannazzisi.
- Do you see that?
- 7 A. Yes.
- Q. Okay. And that's a name that
- 9 you're familiar with, right?
- 10 A. Yes.
- Q. And is it true that this letter and
- maybe some of the additional letters from
- 13 Mr. Rannazzisi have become well-known to
- manufacturers and distributors of opioid
- <sup>15</sup> narcotics? Is that fair?
- MR. HAMMOUD: Object to the form.
- THE WITNESS: I would say that that
- is fair, yeah.
- 19 BY MR. CARTMELL:
- Q. Okay. Now, you weren't working at
- Teva at this time, but let me go through this
- 22 and ask you some questions about it. But first
- it states, Dear sir or madam, this letter is
- being sent to every commercial entity in the

- <sup>1</sup> United States registered with the Drug
- 2 Enforcement Administration to distribute
- 3 controlled substances.
- Now, let me ask you, is it true
- 5 that a pharmaceutical company like Teva or a
- 6 distributor like AmerisourceBergen, they have
- <sup>7</sup> to register with the DEA in order to be allowed
- 8 to sell or distribute opioid narcotics?
- 9 MR. HAMMOUD: Object to the form.
- THE WITNESS: Or manufacture.
- 11 BY MR. CARTMELL:
- 0. Or manufacture?
- 13 A. Correct.
- Q. Okay. It states, The purpose of
- this letter is to reiterate the responsibility
- of controlled substance distributors in view of
- the prescription drug abuse problem our nation
- 18 currently faces.
- Do you see that?
- 20 A. Yes.
- Q. And we've already talked about
- that, but clearly back in 2007, at that point
- 23 already our nation was faced with an opioid
- addiction and abuse problem, correct?

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1
                 MR. HAMMOUD: Object to the form,
2
            lacks foundation.
3
                 THE WITNESS: Well, I'd say that's
            a fair assessment.
5
    BY MR. CARTMELL:
6
                 Okay. And then it states, As each
            Ο.
7
    of you is undoubtedly aware, the abuse or
8
    nonmedical use of controlled prescription drugs
    is a serious and growing health problem in this
10
    country.
11
                 And we've talked about that, and
12
    you agree with that, correct?
13
           Α.
                 Oh, yes.
14
                 The next paragraph states, The
            Ο.
    CSA -- and that would be the Controlled
15
16
    Substances Act, right?
17
           Α.
                 My understanding, yes.
18
                 -- was designed by Congress to
    combat diversion by providing for a closed
19
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- 20 system of drug distribution in which all
- 21 legitimate handlers of controlled substances
- 22 must obtain a DEA registration, and as a
- 23 condition of maintaining such registration,
- 24 must take reasonable steps to ensure that their

- 1 registration is not being utilized as a source
- <sup>2</sup> of diversion.
- Do you see that?
- 4 A. Yes.
- <sup>5</sup> Q. Distributors are, of course, one of
- 6 the key components of the distribution chain.
- 7 If the closed system is to function properly as
- 8 Congress envisioned, distributors must be
- <sup>9</sup> vigilant in deciding whether a prospective
- customer can be trusted to deliver controlled
- 11 substances only for lawful purposes. This
- 12 responsibility is critical as Congress has
- expressly declared that the illegal
- distribution of controlled substances has a
- substantial and detrimental effect on the
- health and welfare of the American people.
- Do you see that?
- 18 A. Yes.
- Q. And what this is talking about is
- that distributors of these drugs and
- 21 manufacturers of these drugs that are selling
- these opioid narcotic drugs have a
- responsibility to try to do everything they can
- to prevent the diversion of the drugs they are

manufacturing, selling, and distributing, 1 2 correct? 3 MR. HAMMOUD: Object to the form. 4 THE WITNESS: Well, I think, you 5 know, doing everything we can, I think 6 that's a fair assessment. 7 BY MR. CARTMELL: 8 Okay. And then if you go to the Ο. 9 next page, I want to talk to you about the 10 second paragraph. Here's where it talks 11 specifically about manufacturers like Teva. 12 In the second sentence it says, 13 Moreover, all registrants -- manufacturers, 14 distributors, pharmacies, and practitioners --15 share responsibility for maintaining 16 appropriate safequards against diversion. 17 Nonetheless, given the extent of prescription 18 drug abuse in the United States, along with the 19 dangerous and potentially lethal consequences 20 of such abuse, even just one distributor that 21 uses its DEA registration to facilitate 22 diversion can cause enormous harm. 23 Do you agree with that? 24 Α. Yes.

- Q. Okay.
- 2 Accordingly, the DEA will use its
- authority to revoke or suspend registrations in
- 4 appropriate cases.
- Do you see that?
- A. Yes.
- Q. And that's a fact, right, that DEA,
- 8 as the enforcer of the law, the Controlled
- 9 Substances Act, if they find that a
- manufacturer of opioids or a seller or
- distributor of opioids is allowing diversion or
- ignoring diversion, or not taking on their duty
- to try to prevent diversion and abuse of these
- drugs, the DEA can take away the registration
- 15 from that company. Is that fair?
- 16 A. They have --
- MR. HAMMOUD: Object to the form.
- THE WITNESS: I believe they have
- that ability, yes.
- 20 BY MR. CARTMELL:
- Q. And taking away a company's reg --
- DEA registration is a really big deal. Would
- you agree with that?
- A. Oh, I would agree with that, yes.

- Q. Because if the registration for the
- 2 company, a company like Teva, is taken away by
- the DEA, then that company no longer has the
- 4 ability to sell or distribute these opioid
- <sup>5</sup> narcotic drugs. Is that fair?
- A. Or manufacture.
- Q. Or manufacture them, right?
- 8 A. Correct.
- <sup>9</sup> Q. The next paragraph, if you look at
- the second sentence, states, Listed first among
- these factors is the duty of distributors to
- maintain effective controls against diversion
- of controlled substances into other than
- 14 legitimate medical, scientific, and industrial
- 15 channels.
- Do you see that?
- 17 A. Yes.
- Q. And does that mean there is a duty
- by distributors and manufacturers of these
- opioids, and sellers of these opioid narcotic
- drugs, that they have to have controls in place
- in their organization to help prevent the
- diversion and abuse of these drugs? Is that
- 24 what that means?

- MR. HAMMOUD: Object to the form.
- MR. NICHOLAS: Object to form.
- THE WITNESS: And I would say
- 4 that's a fair assessment.
- 5 BY MR. CARTMELL:
- Q. Okay. If you go down to the next
- paragraph, it states, The DEA regulations
- 8 require all distributors to report suspicious
- 9 orders of controlled substances.
- Do you see that?
- 11 A. Yes.
- Q. Now, you talked about you were
- actually hired by Teva to be the manager of the
- suspicious order monitoring; is that right?
- A. Of the suspicious order monitoring
- program, yes.
- Q. And when we talk about suspicious
- orders related to opioids, what are we talking
- 19 about?
- A. We're talking about orders that may
- be of an unusual size, pattern, or frequency.
- Q. Okay. And I think it says this
- here. Let's talk about it.
- The registration -- or excuse me.

- 1 The registrant shall design and operate a
- 2 system to disclose to the registrant suspicious
- orders of controlled substances.
- Would you agree with me that it's
- 5 the duty of Teva and all manufacturers and
- 6 sellers and distributors of these opioids to
- <sup>7</sup> design a system so that they can, to the best
- 8 of their ability, have suspicious orders
- 9 identified?
- MR. HAMMOUD: Object to the form.
- THE WITNESS: I would say that's a
- fair assessment, yes.
- 13 BY MR. CARTMELL:
- Q. It then states that the registrant
- shall inform the field division office of the
- administration in his area of suspicious orders
- when discovered by the registrant.
- Do you see that?
- 19 A. Yes.
- Q. And "the registrant" is talking
- 21 about -- in your case Teva would be the
- registrant because they have a DEA
- <sup>23</sup> registration, right?
- A. Correct.

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1
                 So Teva, according to the law
           0.
    that's been in place since the 1970s, has had,
2
3
    one, the duty to design a system that's
    effective in helping them to identify the
5
    diversion of opioids, correct?
6
                 MR. HAMMOUD: Object to the form.
7
                 THE WITNESS: Controlled
8
            substances, yes.
9
    BY MR. CARTMELL:
10
                 Including opioids, right?
            O.
11
           Α.
                 Correct.
12
           Ο.
                 And also they've got to operate a
    system that's effective in disclosing
13
14
    suspicious orders that come to them for these
15
    opioids, correct?
16
           Α.
                 Correct.
```

- 17 Okay. And that's been going on --0.
- that's been the duty of companies like Teva and 18
- distributors of opioids, that duty has existed 19
- 20 since the 1970s, correct?
- 21 MR. HAMMOUD: Object to the form.
- 22 THE WITNESS: I'm not certain when
- 23 the reg came into effect, but I'll take
- 24 your word as an attorney.

- 1 BY MR. CARTMELL:
- Q. Well, you know that that -- and I
- don't mean to put words in your mouth, but I
- 4 take it from your experience, you know that
- 5 this duty that we've been talking about, to
- 6 have a suspicious order monitoring system, one
- <sup>7</sup> that is effective, that duty has been in effect
- 8 since before the 1990s. Fair enough?
- 9 A. Oh, that's fair.
- Q. If you go a couple paragraphs down,
- it says, Thus, in addition to reporting all
- suspicious orders, a distributor has a
- 13 statutory responsibility to exercise due
- diligence to avoid filling suspicious orders
- that might be diverted into
- other-than-legitimate medical, scientific, and
- industrial channels.
- Do you see that?
- 19 A. Yes.
- Q. And that's the law, right?
- MR. HAMMOUD: Object to the form,
- calls for a legal conclusion.
- THE WITNESS: And that's my
- understanding.

- 1 BY MR. CARTMELL:
- Q. I should say that's your
- <sup>3</sup> understanding of the law as a suspicious order
- 4 monitoring manager at Teva. Is that fair?
- 5 A. That is a fair assessment, yes.
- Q. In other words, your understanding
- 7 as the manager at Teva since 2014 has been that
- 8 if your company determines that there are
- 9 suspicious orders for opioid narcotic drugs
- that has come to your company, you have the
- duty to report that to the DEA, correct?
- MR. HAMMOUD: Object to the form.
- THE WITNESS: That is correct.
- 14 BY MR. CARTMELL:
- Q. And is it true that you also have
- the duty -- when your company determines that
- one of your customers has a suspicious order,
- you have the duty to, in fact, stop that order
- 19 from being shipped so that it won't likely be
- diverted out in the community?
- MR. HAMMOUD: Object to the form,
- calls for a legal conclusion.
- THE WITNESS: Yeah, I haven't heard
- that there's a regulatory requirement to

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1
           stop it, but I will say that I don't
2
           ship anything that we have determined to
3
           be suspicious.
    BY MR. CARTMELL:
5
                 In other words, would you agree
           Ο.
6
    with me that the most prudent practice and the
7
    most responsible practice would be that if a
8
    company like Teva and its manager like you
9
    determines that orders are suspicious for these
10
    opioids that are narcotics and that you know
11
    can be diverted and abused so readily, the best
12
    practice and the most responsible practice
13
    would be not to ship those orders? Do you
14
    agree with that?
15
                 MR. HAMMOUD: Object to the form.
16
                 THE WITNESS: I would agree to
17
           that.
18
    BY MR. CARTMELL:
                 Okay. It then states, In a similar
19
    vein, given the requirement under Section
20
21
    823(e) that a distributor maintain effective
22
    controls against diversion, a distributor may
23
    not simply rely on the fact that the person
    placing the suspicious order is a DEA
24
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- 1 registrant and turn a blind eye to the
- <sup>2</sup> suspicious circumstances.
- Do you see that?
- 4 A. Yes.
- <sup>5</sup> Q. In other words, that means that a
- 6 company like Teva, if you have an order for
- opioids that you think may be suspicious and
- 8 could likely be diverted or abused out in the
- 9 communities, you can't turn a blind eye and
- just say, well, I'll go ahead and ship it
- because the person who made the order is
- 12 registered with the DEA. You can't do that,
- 13 right?
- MR. HAMMOUD: Object to the form.
- THE WITNESS: And I would say that
- yes, that is correct.
- 17 BY MR. CARTMELL:
- Q. And just on the -- I don't want to
- 19 go through them, but if you turn the page,
- Mr. Tomkiewicz, you'll see that there are
- 21 actually some hints by the DEA here that were
- given to distributors and manufacturers of
- these opioids as far as some things that might
- be a clue that an order might be suspicious or

- 1 may be ultimately diverted.
- Do you see that?
- A. Yes.
- Q. You can see that they give
- 5 circumstances that might be indicative of
- 6 diversion, right?
- A. Correct.
- Q. And you're very familiar with those
- 9 circumstances, I take it?
- 10 A. Yes, I'm familiar with them.
- Q. And you take those circumstances or
- these hints that are given by the DEA into
- consideration as the manager that is monitoring
- suspicious orders. Is that fair to say?
- 15 A. These specifically, when I'm
- 16 reviewing -- when we're reviewing things that
- might be suspicious, I wouldn't say we refer
- back to this document, but they're often
- included in, you know, how we review.
- Q. Okay. In other words, you're
- saying, I don't get the document out, but these
- are some of the things we look for when we're
- looking for a suspicious order of opioid
- narcotic drugs, right?

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1
           Α.
                Or any controlled substance, yes.
                Okay. Now, if you go back to the
2
           Ο.
    first page, this letter, which is often
    referred to as the Rannazzisi letter, was --
5
    well, let me ask you if you agree with me.
6
                 This letter that was sent from the
7
    Drug Enforcement Administration to all of the
    manufacturers and sellers and distributors of
8
9
    opioids, including the high-risk opioids that
10
    are narcotics and easily diverted, this was
11
    sort of a reminder to these manufacturers,
12
    sellers, and distributors of the
13
    responsibilities and duties they had to help
14
    prevent diversions of opioids. Would you agree
15
    with that?
16
                MR. HAMMOUD: Object to the form.
17
                 THE WITNESS: And I would not agree
18
           with the assessment in your question
19
           that certain high-risk, at least as I
20
           define them, are easily diverted.
21
    BY MR. CARTMELL:
22
           Ο.
                 Okay, well, let me restate --
23
           Α.
                 -- I would --
```

Fair enough.

Ο.

24

- A. Yeah, I would reject that.
- Q. Fair enough. Let me restate the
- <sup>3</sup> question.
- 4 Would you agree with me that this
- <sup>5</sup> letter that's often referred to as the
- 6 Rannazzisi letter was the Drug Enforcement
- 7 Agency sending a letter to manufacturers,
- 8 distributors, sellers of opioid narcotic drugs
- 9 as sort of a reminder and reiterating the
- duties and responsibilities that they had to
- try to prevent the diversion of opioid narcotic
- 12 drugs? Fair enough?
- MR. HAMMOUD: Object to the form.
- 14 THE WITNESS: And I would say
- that's a fair assessment.
- 16 BY MR. CARTMELL:
- Q. Okay. Do you know, as you sit here
- 18 today, when it was that Teva first started
- 19 selling or distributing opioids?
- A. No, I don't.
- Q. Do you have any clue?
- MR. HAMMOUD: Objection, asked and
- answered.
- THE WITNESS: I have no idea.

- 1 BY MR. CARTMELL:
- Q. Okay. It should be noted, though,
- 3 I think, that when you arrived at Teva in 2014,
- 4 at that point I take it you know that they were
- 5 selling lots of different Class II opioid
- 6 products. Is that fair?
- 7 MR. HAMMOUD: Object to the form,
- 8 lacks foundation.
- 9 THE WITNESS: And -- sorry, but I
- don't like the term "lots." I like
- using numbers.
- 12 BY MR. CARTMELL:
- Q. Well, I counted, from the documents
- 14 I received, that today, Teva is selling, I
- believe, 18 or 19 Class II opioid narcotic
- drugs. Is that consistent with your
- understanding?
- 18 A. That could be consistent, yes.
- Q. And I said "lots." But when you
- <sup>20</sup> arrived in 2014, is it fair to say that Teva
- was selling a number of different opioid --
- <sup>22</sup> Class II opioid narcotic drugs? Fair to say?
- MR. HAMMOUD: Object to the form.
- THE WITNESS: I would say that's

- fair to say.
- 2 BY MR. CARTMELL:
- Q. And fair to say that Teva sells and
- 4 distributes millions of prescriptions for
- <sup>5</sup> opioid narcotic drugs? Fair?
- 6 MR. HAMMOUD: Object to the form.
- 7 THE WITNESS: We don't dispense
- prescriptions.
- 9 BY MR. CARTMELL:
- Q. Bad question. Thank you for
- 11 correcting that.
- 12 Is it fair to say that Teva sells
- and distributes millions and millions of opioid
- 14 narcotic drug pills per year?
- MR. HAMMOUD: Object to the form.
- THE WITNESS: I haven't looked at
- the specific number of dosage units, but
- 18 I'm sure it's in the millions. But
- beyond that, I couldn't say millions and
- millions. And to say -- we've sold a
- good number of them.
- 22 BY MR. CARTMELL:
- Q. And I think I've seen data that
- suggests that today, or since 2016, Teva has

- been, as far as the sales of opioid drugs,
- about at the 9 to 10 percent of the sales are
- of Teva opioid products. Is that consistent
- with your understanding?
- MR. HAMMOUD: Object to the form,
- 6 lacks foundation.
- 7 THE WITNESS: I don't know that
- offhand.
- 9 BY MR. CARTMELL:
- Q. But you agree that Teva is one of
- the larger sellers and distributors of opioid
- 12 narcotic drugs in America, correct?
- 13 A. I would say that's a fair
- 14 assessment, yes.
- Q. And those are all things that, when
- you came to Teva, some of the things that you
- looked into, I take it, and learned as you
- 18 started in your job as the new suspicious order
- 19 manager; is that right?
- A. Right. Well, looking at the -- you
- 21 know, which specific products we were selling,
- which, of course, was a different mix when I
- started from what is currently being sold.
- Q. We talked about the law, the

- 1 Controlled Substances Act, and the DEA
- 2 enforcement of a law related to the sales of
- opioids in America. And is it true that the
- 4 DEA has actually left the responsibility to the
- 5 manufacturers and sellers and distributors of
- opioids to design, internally, systems to help
- 7 prevent opioid diversion?
- 8 MR. HAMMOUD: Objection to the
- 9 form.
- THE WITNESS: Could you ask that
- again? I got lost in the question.
- 12 BY MR. CARTMELL:
- Q. Sure. Is it true that the DEA has
- left the responsibility or relies on the
- manufacturers and distributors and sellers of
- opioid narcotic drugs in America to develop the
- systems to help divert -- their internal
- 18 systems to help divert opioids -- help to
- 19 prevent the diversion of opioids?
- 20 A. So are --
- MR. HAMMOUD: Same objection.
- THE WITNESS: Yeah, are you saying
- that the DEA has sort of left the
- manufacturers on their own to develop

```
1
            their own system to detect potential
2
            diversion?
    BY MR. CARTMELL:
                 Let me restate the question to make
5
    it more clear.
6
                 As we saw from the Controlled
7
    Substances Act, it requires manufacturers like
8
    Teva to develop internal systems that will
    help, for one thing, identify suspicious orders
10
    of opioids, right?
11
           A.
                 Correct.
12
                 It also said in the Controlled
           Ο.
13
    Substances Act that manufacturers like Teva who
14
    sell opioids have to design systems internally
15
    to help prevent the diversion of opioids,
16
    correct?
17
                 MR. HAMMOUD: Object to the form.
                 THE WITNESS: Of any controlled
18
19
            substance.
20
    BY MR. CARTMELL:
21
                 Including opioids, right?
            Q.
22
           Α.
                 Yes.
23
                 And is it true that the DEA
           Q.
```

actually relies on Teva and the individual

24

- 1 manufacturers and sellers and distributors of
- opioids to, in fact, develop those systems and
- make sure they have effective systems in place
- 4 and monitoring programs in place so that they
- 5 can help divert the -- or help prevent the
- 6 diversion of opioids?
- 7 MR. HAMMOUD: Same objection.
- 8 THE WITNESS: And I wouldn't say --
- 9 I couldn't say that the DEA relies on
- manufacturers and distributors for that.
- Because when it comes to suspicious
- order monitoring, they really haven't
- given any feedback.
- 14 BY MR. CARTMELL:
- Q. Okay. But you know from the
- 16 Controlled Substances Act that you have to have
- 17 systems in place --
- 18 A. Correct.
- Q. -- right? And the DEA does not
- develop those systems for you, correct?
- A. The DEA has not developed our
- system, no.
- Q. Okay. And so you are left as a
- manufacturer, meaning Teva, of these opioids to

```
develop those systems yourself, correct?
1
2
           Α.
                 Correct.
3
                And the DEA does rely on each of
            Ο.
    the companies like Teva to develop those
5
    systems to help prevent opioid diversion,
6
    correct?
7
                 MR. HAMMOUD: Object to the form.
8
                 THE WITNESS: Well, and again, I
9
           can't say that the DEA relies on because
10
            I don't know what the DEA is doing on
           their end. So in terms of, you know,
11
12
            saying that the DEA relies on, you know,
13
           manufacturers or distributors or even
14
           down to pharmacies or practitioners, I
15
            can't say that.
16
    BY MR. CARTMELL:
17
            Ο.
                 Okay. One of the things, though,
    that companies like Teva, as we discussed, are
18
    interested in is maximizing the sales of their
19
20
    prescription drugs like opioids, including
21
    opioids, correct?
22
                 MR. HAMMOUD: Object to the form,
23
            lacks foundation.
24
                 THE WITNESS: Maximizing?
                                             I think
```

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that's a horrible word for it. No
```

- offense, but...
- 3 BY MR. CARTMELL:
- 4 Q. How would you describe it?
- 5 A. Companies want to increase
- 6 profitability. That's the reason why people
- <sup>7</sup> are in business.
- Q. Mr. Tomkiewicz, the DEA, as we saw,
- 9 has told Teva and companies like Teva who sell
- and distribute opioids to set up systems that
- will identify suspicious orders of opioids,
- 12 correct?
- 13 A. Correct.
- Q. And they've asked those companies
- to take it upon themselves to provide the
- 16 resources and actual processes to put in
- effective types of monitoring programs to find
- 18 suspicious orders, correct?
- MR. HAMMOUD: Object to the form.
- THE WITNESS: I would say that's a
- fair assessment.
- 22 BY MR. CARTMELL:
- Q. And these same companies that the
- DEA has asked to set up these systems so that

- they can find these suspicious orders are
- 2 companies like Teva who, as you said, are
- interested in maximizing their profits,
- 4 correct?
- A. I never said that.
- MR. HAMMOUD: Objection,
- mischaracterizes his testimony.
- 8 THE WITNESS: In fact, I
- 9 categorically denied the word
- "maximize."
- 11 BY MR. CARTMELL:
- Q. How did you describe it? I'll use
- your words.
- 14 A. I said that any company wants to
- increase profits. That's why you're in
- business.
- Q. So these companies that the DEA has
- asked to set up these systems to help prevent
- the diversion of opioids are the same companies
- that want to increase their profits, correct?
- A. I think that's a goal of business.
- Q. And part of increasing profits, as
- we've discussed, is potentially, or can be,
- increasing their sales, correct?

- 1 A. Correct.
- 2 O. So they're asking companies that
- want to increase their sales and increase their
- 4 profits to set up systems that could, if they
- <sup>5</sup> find suspicious orders, decrease their sales,
- 6 correct?
- 7 MR. HAMMOUD: Object to the form.
- 8 THE WITNESS: Well, and that's --
- 9 that is correct. I would say that's a
- fair assessment.
- 11 BY MR. CARTMELL:
- Q. So these same companies that
- they're saying that we want you to identify
- these orders that are suspicious, and we want
- you to make sure that they are stopped so
- they're not diverted, are the same companies
- that want to increase sales and increase
- profits over time, correct?
- A. Well, it's going to be difficult to
- increase sales if you don't have a DEA
- <sup>21</sup> registration.
- Q. I understand that, but my point is
- simply that there is an inherent conflict in
- that system, correct?

```
Well, that's what I'm saying.
1
           Α.
    There isn't an inherent conflict.
2
3
           O. You don't believe that's a conflict
    or sort of, so to speak, the fox guarding the
5
    hen house?
6
           Α.
                No.
7
                MR. HAMMOUD: Object to the form.
8
                MR. CARTMELL: How long have we
9
           been going?
10
                MR. HAMMOUD: About an hour and
11
           three minutes.
12
                MR. CARTMELL: Do you want to take
13
           a quick break?
14
                 THE WITNESS: A break sounds good.
15
                MR. CARTMELL: Like ten minutes?
16
                VIDEO OPERATOR: Going off the
17
           record, 2 p.m.
18
                 (Recess from 2:03 p.m. until
19
           2:15 p.m.)
20
                VIDEO OPERATOR: Back on record at
21
           2:15 p.m.
22
    BY MR. CARTMELL:
23
           Q. Mr. Tomkiewicz, we're back on the
24
    record. Are you ready to proceed?
```

- A. Yes, I am.
- Q. I want to ask you a few more
- questions about Exhibit 3. I think it's in
- 4 front of you. And this was the PowerPoint
- 5 presentation from March of 2014, which was just
- a few months after you arrived at the company
- 7 to start working, correct?
- 8 A. Correct.
- 9 Q. And if we look at page 3, as we
- discussed, there was a proposed DEA compliance
- organization, and as we discussed, there was a
- small restructuring or a few people moving
- around, according to this proposed
- organization; is that correct?
- A. Correct.
- Q. And did that small restructuring
- occur at that time; do you know?
- A. I believe it did.
- Q. Okay. And if you look at where you
- are, Joe Tomkiewicz, it states under you, you
- had one individual reporting to you, Matt
- Benkert; is that right?
- A. That's correct.
- Q. And his position was -- it

- indicates he's an investigator; is that right?
- A. Correct.
- 3 Q. So does that mean that he would be
- 4 somebody who would actually be involved in
- 5 investigating the suspicious orders?
- A. Potential suspicious orders.
- <sup>7</sup> Q. Okay.
- 8 A. Investigating orders to determine
- 9 if they're suspicious.
- Q. I got you. Okay. And we'll talk
- about that process more, but I think what
- you're talking about is orders would be
- sometimes flagged or pulled aside or pended
- 14 after going through the computer system or the
- algorithm, and then there would be an
- investigation of that to see if it was
- suspicious or not, correct?
- 18 A. Correct.
- Q. Okay. Now, how many actually of
- the 16 employees in this organization or this
- department were actually involved in the
- investigation of suspicious orders or pended
- orders?
- A. Oh, of pended orders? It was

- primarily -- primarily Matt and myself.
- Q. Okay. So of the 16 individuals
- indicated in the organization as of March of
- 4 2014, it sounds like what you were saying is
- 5 you and your direct -- well, the person who was
- 6 directly under you, Matt, were the two that
- 7 would actually take on the job of investigating
- 8 whether or not orders from customers for
- <sup>9</sup> opioids were suspicious or not. Is that fair?
- 10 A. That is fair.
- Q. Okay. And if you go to the next
- page of this PowerPoint, it talks about
- predictions, and then it states, Controlled
- substances Teva, 13 sites with DEA
- 15 registrations.
- Do you see that?
- A. Yes.
- O. What does that mean?
- A. 13 locations, each with an
- <sup>20</sup> individual DEA registration.
- Q. Okay. And so you had 13 different
- sites that were distributing opioids or
- narcotics and were DEA registered; is that
- 24 correct?

1 Α. No. 2 MR. HAMMOUD: Object to the form. 3 THE WITNESS: No, that's not correct. 5 BY MR. CARTMELL: 6 Okay. Well, 13 -- strike that. Q. 7 It also states that you have a 8 total of 44 DEA registrations. 9 Do you see that? 10 Α. Yes. 11 Okay. And so you had 16 people 12 that were in charge of what, with respect to 13 the DEA registrations? Was it to make sure 14 they were in compliance? 15 MR. HAMMOUD: Object to the form. 16 THE WITNESS: Well, it depends upon 17 the person and their specific responsibilities and their location. 18 19 BY MR. CARTMELL: 20 Okay. As far as your DEA Q. 21 compliance group, is it true that those 16 22 employees were located in lots of different 23 locations? 24 In different locations, yes. Α.

- Q. Okay. Was Colleen McGinn in the
- same location as you?
- 3 A. No.
- Q. Okay. And where was she located?
- 5 A. I believe she's in the Frazer
- 6 location.
- Q. Okay. But there wasn't one
- 8 centralized location for all of the DEA control
- 9 employees; they were spread out among the
- different offices, correct?
- MR. HAMMOUD: Object to the form.
- THE WITNESS: Correct.
- 13 BY MR. CARTMELL:
- 0. Is that correct?
- A. That's -- is correct.
- Q. It says, CS -- that stands for
- controlled substances, correct?
- 18 A. Yes.
- Q. -- represent X percent of Teva
- 20 sales. What does that mean?
- A. I don't know specific. I can make
- <sup>22</sup> a conjecture.
- 23 Q. Okay.
- A. That this is a draft.